GCP Compliance Manager

Reports to: Vice President of Quality

Classification: Exempt

Summary:
Responsible for the execution of the global Quality Assurance (QA) audit activities, for Good Clinical Practice (GCP) oversight, and for assuring the compliance of studies with CymaBay Therapeutics, Inc. policies, and all applicable worldwide regulations and guidelines (e.g. US FDA, EU Directives, ICH, and National regulations).

Essential Functions and Job Responsibilities:

- Represents GCP QA and provides QA guidance for project/study teams with participation in the applicable forums, providing GCP compliance input and guidance to stakeholders, to achieve continuous quality improvement and effective quality controls
- Interface with relevant stakeholders, including regulatory, clinical and development sub-teams, as appropriate to provide Good Clinical Practice, and QA compliance expertise
- Ensure appropriate and timely escalation of quality issues, including potential misconduct or issues of significant deviation with projects/products
- Participate in the development of the GCP systems, risk assessment and identification of areas to be audited
- Assist in the management of GCP systems including but not limited to CAPAs, Deviations, etc.
- Conduct QA GCP audits (Investigator Site, Vendor, Internal process, For-cause, and directed/complex audits), generates audit reports, communicates results to the relevant QA management and external relevant stakeholders, and interacts with various teams to ensure corrective and preventative actions are taken to bring QA GCP observations to closure, as applicable
- Participate in the development/enhancement of QA GCP procedures, guidance documents and audit tools to ensure QA consistency
- Provide inspection management support, as appropriate
- Provide or coordinates GCP training and Mock Inspection preparation support, as needed
- Manage consultants for execution of GCP audits, as applicable
- Complete other responsibilities as assigned and agreed upon

Minimum Qualifications:

- Bachelor's degree in a scientific discipline or equivalent qualification
- 6-8 years specific experience in GCP quality assurance auditing and compliance or equivalent experience
- Comprehensive working knowledge of GCP related regulatory requirements US FDA, EU Directives and ICH guidelines
- Auditor training or certification a plus
- Prior experience in regulatory inspections a plus
- Experience working in lean fast paced environment with multiple priorities
- Demonstrated ability to manage priorities, multi-task and follow projects through to completion
- Ability to travel 40% domestically and internationally